Amendments

Please amend the claims as shown below.

1. (previously presented) A method for-extracorporeal blood treatment, comprising the steps of:

providing a blood treatment machine including at least one pump and a disposable filter; a fluid circuit including a blood withdrawal line, a blood return line, and a

waste line being connected to said filter;

a replacement fluid line connected to said tubing set to dilute blood carried in at least one of said blood return and blood withdrawal lines;

connecting the patient's vascular system to the blood withdrawal and return lines;

engaging a single member carrying said waste, replacement fluid, and blood withdrawal lines to a treatment machine;

the member and treatment machine being configured such that by said step of engaging a single member, said at least one pump is enabled to pump fluid through said waste, withdrawal and return lines;

withdrawing blood through a blood withdrawal line at a rate of at least 300 ml/mm passing the blood through a filter to remove waste; and

passing the filtered blood through a blood return line and into the patient, wherein blood is withdrawn from and returned to the patient continuously for about 1.5 hours, and wherein the blood flow rate is at least 400 ml./min.

2-3 (Canceled)

4. (previously presented) The method of claim 1, wherein the blood withdrawal line, the filter, and the blood return line are pre-attached and disconnectable from said treatment machine.

5. (Original) The method of claim 1, wherein an amount of replacement fluid is added to the blood, and wherein the amount id determined by gravimetric balancing of the replacement fluid and the waste.

6. (Original) The method of claim 1, further comprising step of repeating the procedure at least daily.

7. (Original) The method of claim 1, wherein the procedure is conducted at home.

8. (Original) The method of claim 5, wherein the amount of the replacement fluid is approximately 9-13 liters.

9. (Original) The method of claim 5, wherein the replacement fluid is added to the blood after filtration.

10. (Original) The method of claim 1, further comprising the step of repeating the procedure for more than one week.

11. (Original) The method of claim 1, further comprising the steps of connecting the blood withdrawal line to the patient and connecting the blood return line to the patient.

12 (Original) the method of claim 11, wherein the blood withdrawal line and the blood return line are connected to the patient through a subcutaneous port.

13. (currently amended) A method for hemofiltration, comprising the steps of:

withdrawing blood through a blood withdrawal line at a rate of at least 300 ml/min.;

passing the blood through a filter to remove waste;

and passing the filtered blood through a blood return line and into the patient, wherein blood is withdrawn from and returned to the patient continuously for about 1.5 hours, and wherein the blood flow rate is at least 400 ml./min;

pumping the withdrawn blood with a pump at a predetermined blood flow rate;

measuring the actual blood flow rate delivered by the pump using a flow sensor;

comparing the actual blood flow rate with a blood flow rate indicated by a pump speed; and

activating an alarm responsively to a ~~when the~~ difference between the actual blood flow rate indicated by said flow sensor and ~~with~~ the blood flow rate indicated by a pump speed such that said alarm is activated when said difference exceeds a predetermined value.

14. (previously presented) The method of claim 1, wherein the blood withdrawal line and the blood return line are in registry with said at least one pump and said at least one pump includes a peristaltic pump.

15. (original) The method of claim 1, wherein at least one of the blood withdrawal line and the blood return line further comprises a leak detector.

16 - 18 (canceled)

19. (new) A method as in claim 13, further comprising determining a pressure responsively to said difference.

20. (new) A method for-extracorporeal blood treatment, comprising the steps of:

providing a blood treatment machine including at least one pump and a disposable filter; a fluid circuit including a blood withdrawal line, a blood return line, and a

waste line being connected to said filter;

a replacement fluid line connected to said tubing set to dilute blood carried in at least one of said blood return and blood withdrawal lines;

connecting the patient's vascular system to the blood withdrawal and return lines;

fastening a member carrying said waste, replacement fluid, and blood withdrawal lines to a treatment machine; the member and treatment machine being configured such that by said step of connecting, said waste, withdrawal, and return lines are engaged by, and actuated by, said pump;

withdrawing blood through a blood withdrawal line at a rate of at least 300 ml/mm passing the blood through a filter to remove waste; and

passing the filtered blood through a blood return line and into the patient, wherein blood is withdrawn from and returned to the patient continuously for about 1.5 hours, and wherein the blood flow rate is at least 400 ml./min.

Claim Rejections – 35 USC §103

Claim 1 stands rejected as obvious over Ash (US 5,536,412). Essential to the Office Action's argument for rejection is that (quoting the office action):

> Amended claim 1 recites the step of 'engaging a single member carrying said waste, replacement fluid, and blood withdrawal lines to a treatment machine; the member and treatment machine being configured such that by said step of engaging a single member, said at least one pump is enabled to pump fluid through said waste, withdrawal, and return lines.' Ash discloses ... a disposable dialysis cartridge (seen as applicant's 'single member') having tubing lines attached thereto. Ash teaches that the cartridge is attached to the dialysis treatment machine thereby engaging the cartridge and treatment member and at the same time placing the cartridge and tubing in communication with the pump(s) such that the pump(s) are enabled to pump fluid through the tubing.

Applicants note that claim 1 recites "a single member carrying said waste, replacement, and blood withdrawal lines ... the member and treatment machine being configured such that by said step of engaging a single member, said pump is enabled to pump fluid through said waste, withdrawal, and return lines." The Office Action's identifies the recited "single member" with Ash's "disposable dialysis cartridge." First Ash does not have such an element. In the incorporated reference, US 4,661,246, Ash shows a cassette 23 (Fig. 2) which appears to hold the components of the fluid circuit. But there is no disclosure in this reference of "the [cassette] and treatment machine being configured such that by said step of engaging [the cassette], said at least one pump is enabled to pump fluid through said waste, withdrawal, and return lines." Certainly

we can infer that if the cassette, including waste, withdrawal, and return lines connected to it, are engaged, then an "at least one pump [will be] enabled to pump fluid ..." but this assumes that the member ***carries*** the waste, withdrawal, and return lines, and ***is***, the waste, withdrawal, and return lines which is logically inconsistent.

Put another way, if we assume the entire fluid circuit is what the Office Action proposes to identify with the recited "single member" then the recited fluid lines would have to be subsumed by the "member." The claim plainly does not allow such an interpretation because it would contradict the recitation "a single member carrying said waste, replacement, and blood lines" which indicates the member and the elements it carries are separate elements. Applicants therefore propose the rejection of claim 1 is in error and request that the rejection of claim 1 and its dependent claims 4-12 be withdrawn. If the cassette alone, separate and apart from the tubes it carries is identified with the "member," then there is no disclosure of "the [cassette] and treatment machine being configured such that by said step of engaging [the cassette], said at least one pump is enabled to pump fluid through said waste, withdrawal, and return lines."

Claim 13 was rejected based on the argument (quoting the Office Action): "At the time of the invention it would have been obvious to one having ordinary skill in the art to modify the controller of Ash to include an alarm function as taught by Kitaevich et al., since it is important to monitor and be alerted to high blood flow rates." The alarm function of Kitaevich is, in the words of the Office Action, "a pressure transducer in the tubing to measure pressure (i.e. blood flow pressure). From the signals, the controller determines the actual blood flow pressure and determines if it is within or outside of the pressure limits. If it exceeds the preselected limits an

alarm sounds." Combining Ash with the teachings of Kitaevich would not result in the invention claimed, even if one measured parameter is taken as equivalent to another for purposes of the alarm response. This is because while Kitaevich compares a pressure with a predetermined level, or more generally as the Office Action stipulates, compares a measured parameter with a predetermined value, the claim recites "measuring the actual blood flow rate delivered by the pump using a flow sensor; comparing the actual blood flow rate with *a blood flow rate indicated by a pump speed*; and activating an alarm when the difference between the actual blood flow rate with ***the blood flow rate indicated by a pump speed*** exceeds a predetermined value." In Kitaevich, the level being compared to the measured parameter is "predetermined" exactly as indicated in the office action. In the claim, the measured flow rate is compared to a flow rate indicated by the pump speed. If a line were partially blocked, the flow sensor would tend to show a slower speed than the pump, but the pump speed may also change as it strains against the higher pressure. If feedback control, as taught by Kitaevich, were applied in that context, the pump speed would not matter because the alarm would go off when the flow dropped to some predefined limit. The pump speed is not a predetermined limit as used in feedback control. To emphasize the difference, claim 13 has been amended to recite the alarm is "responsive" to a difference between the pump speed and the measured flow. For the foregoing reasons, the rejection of claim 13 is traversed and withdrawal of the rejection is requested.

New claim 19 is supported at least by paragraph 60 of the published specification (US20010037079). New claim 20 is considered patentably distinct from the references at least because the prior art does not show or teach "fastening a member carrying said waste,

replacement fluid, and blood withdrawal lines to a treatment machine; the member and treatment machine being configured such that by said step of connecting, said waste, withdrawal, and return lines are engaged by and actuated by said pump" as recited by the claim.

If the Examiner requires clarification of any issues raised in this response, the Examiner is invited to call the undersigned at (202) 778-1118.

Respectfully submitted,

PROSKAUER ROSE, LLP

Dated: March 15, 2005 By: _____

Mark A. Catan
Reg. No. 38,720
Proskauer Rose, LLP
1585 Broadway
New York, NY 10036-8299